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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,593	06/12/1998	STEPHEN D. O'CONNOR	A-64559-3/RT	1989

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EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/096,593

Applicant(s)

O'CONNOR ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22,23 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22,23 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2005 has been entered.

Amendment Entry

2. The amendment filed under 37 CFR 1.116 on April 25, 2005 has been entered. Claim 20 and 30 were modified. New claim 36 was added while claims 1-19, 21 and 24-29 were canceled. Accordingly claims 20, 22, 23 and 30-36 are pending and under consideration.
3. Rejections of record not reiterated herein have been withdrawn.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.
5. The IDS filed June 24, 2005 has been considered as to the merits prior to Final Action.

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Remarks

6. Applicant's have indicated that claim 20 and 30-33 were previously amended to recite "passivation agent monolayer" to replace "self-assembled monolayer" in response to recent written description requirements and because the definition for the terms are identical (paper filed 8/11/03). It is noted that no written description rejection is set forth in the prior Office Action mailed April 19, 2003 and a definition citing Applicants intended identical scope of the terms was not found in the disclosure. Applicant is invited to show identical definition of the terms "passivation agent monolayer" to replace "self-assembled monolayer" in the disclosure.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 20, 22-23 and 30-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant has changed the claim language to read on "passivation monolayer" replacing self assembled monolayer (SAM). However, the interchangeable modification of the two terms is not support by the disclosure. The specification implies that the passivation agent is a spacer not a replacement for the SAM. Applicant is invited to show support for the identical definitions of the two terms, "passivation monolayer" and self assembled monolayer (SAM). This is deemed new matter.

Response to Arguments

Applicant contends that self assembled monolayer and passivation agents are described in the specification. Although the specification does not specifically recite that the two terms are interchangeable, one reasonably skilled in the art would recognize that the inventor intended the same subject matter. This argument was carefully considered but not found persuasive because it must be clear from the application as filed that applicant intended a particular definition, in order to avoid as issue of new matter and/or lack of written description. See MPEP 2163.07 The specification does not clearly set forth that SAM and passivation agents are the same. The passivation agent is taught to be a spacer interchangeable with a conductive oligomer or insulator. Examiner has not found evidence in the specification or the prior art to support the interchange of a passivation monolayer with a SAM. Further, patentability cannot be predicated upon an advantage or result that has not been expressly or at least implicitly disclosed in the application as filed. *Clinical Products v. Brenner*, 255 F.Supp. 131, 149 USPQ 475, 480, (DDC1966). In order for the terms to be recognized as inherent, they must necessarily and always be present and would have been recognized as such by those skilled in the art. Applicant has not provided such evidence. The rejection is maintained.

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8. Claims 20, 22-23 and 30-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been modified to read on a passivation monolayer comprising two covalently attached passivation species and a protein binding ligand. However, Applicant has not cited support for the new claim limitation and examiner was unable to find support. Therein the limitation is considered new matter. Applicant is invited to show support for this limitation.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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I. Claims 20, 30, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) – Abstract Only.

Hollis et al. disclose an apparatus (sensor array) meeting the instantly claimed limitation. The apparatus includes a test chamber with an array of first measuring electrodes (test sites), a passivation agent monolayer, a binding ligand covalently attached to the electrode via a spacer, a voltage source and an electronic detector. See abstract, figure 26 A and page 24 lines 5-25 for spacer definition. Ligands useful in this apparatus include proteins (peptides). See page 1 lines 10-13. The test sites are monolithic structures on semiconductor chips or wafers (test chambers). Binding of the test sites is measured by two electrodes at each test site. See page 4 lines 5-9 and line 16. The test site may be employed to identify target molecules such as polynucleotides, DNA, RNA, cells, antibodies, or anti-antibodies. See page 8 lines 20-22. Two electrodes at each test site measure the binding of the target to the test site. See page 4 lines 5-9 and line 16.

The test site also includes upper and lower electrodes covered with a film and measures voltages in relationship to target molecule binding, hybridization, or interaction. See page 11 lines 14-32. The sensor array contains binding ligands (such as short oligonucleotide strands) attached to the test site. See page 13 lines 11-21.

The arrays are not limited to only oligonucleotide reagents but can be other ligands to make different probes. The probes can be attached directly to the electrodes or solid support substrates (spacer) via covalent linkage. See page 24 lines 5-25.

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In one embodiment the sensor array probes include a aestivating layer (passivation agent monolayer). See figure 26 and page 29 line 27-30. The sensors can be evaluated with a microfluidic detector. See page 34-35, for example.

The passivation layer is taught to be useful in increasing the life of the electrode. See page 44 lines 6-9.

Hollis et al. differ from the instant invention in not specifically teaching that the passivation layer (passivation agent monolayer) comprises two passivation species.

However, Agladze discloses that passivation films (layers) can modified electrode reactivity reactions via OH ions (species one) and anions (species two). See abstract.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the OH ions (species one) and anions (species two) taught by Agladze et al. into the passivation layer apparatus/device of Hollis et al. in order to modify electrode reactivity reactions. See abstract of Agladze.

One of skill in the art would have been motivated to modify the electrode reactivity to determine the optimal electrode reaction parameters.

II. Claims 22-23 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) – Abstract Only as applied to claims 20, 30, 34, and 36 above, and further in view of Kayyem et al. (U.S. Patent #6,221,583) and Kossovsky et al. (U.S. Patent #5,585,646).

Please see Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) as set forth above.

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Hollis et al. (WO 93/22678) differ from the instant invention in failing to specifically teaching passivation agent monolayer or self-assembled monolayer devices/apparatus including insulators and/or conductive oligomers.

However, Kayyem et al. teach devices which include both insulators and conductive oligomers. Kayyem et al. further disclose that oligomers can exits in the apparatus as an insulator. See column 6 lines 24-57 and column 22 line 66 through column 24 line 42.

While, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semi conductive material (applicants monolayer) and a electronically active biochemical molecule (applicants binding ligand) which is bound to the semi conductive surface of an electronic device (applicants electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturization of the electronically active biochemical molecule (Abstract).

The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macromolecules with carbohydrate like components. Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods.

Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) – Abstract Only and further in view of Kayyem et al. (U.S. Patent #6,221,583) and Kossovsky et al. (U.S. Patent#5,585,646) are analogous art because they are from the same field of endeavor, all the inventions teach the fabrication/utility of electrochemical biosensors.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the insulators and/or conductive oligomers taught by Kayyem et al. and Kossovsky et al. in the apparatus/device of Hollis et al. to perform analyte detection in an affinity assay system because Kayyem et al. taught that insulators serve to inhibit or slow electron transfer (column 24 lines 25-27) and conductive oligomers increase the rate of electron transfer and are more conductive than the insulators (column 6 lines 25-47). Further, Kossovsky et al. disclosed that the use of self assembled monolayer (reading on passivation agents or a type of SAM) allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self-assembled monolayer beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossovsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).

One of ordinary skill would have been motivated to employ insulators and or conductors (oligomer) to control electron transfer in binding systems like the one of Hollis et al. to ensure optimal working ranges for precise and accurate evaluation of an analyte of interest.

III. Claim 35 is rejected under 35 U.S.C.103(a) as being unpatentable over Hollis et al. (WO93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) and further in view of Wohlstadter et al. (U.S.Patent#6,090,545).

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Please see Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) as set forth above.

Hollis et al. (WO 93/22678) in view of Agladze (Metallurgy and Foundry Engineering, 1997, 23(2), 127-137) differ from the instant invention in failing to specifically teach a processor for data analysis in their device designs.

However, Wohlstadter et al. disclose patterned, multi-array multi-species surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence (ECL) based tests. The PMAMS can be generated from self- assembled monolayer on a surface. (column 13, lines 10-31). In figure 47 shows an embodiment in which the multi-array apparatus/device includes a microprocessor/computer containing controller means for generating and analyzing ECL signals. See column 7 lines 38-40. The apparatus further provides a voltage source and photon detector. Column 3 lines 59-65 and column 22 Voltage Waveform.

Hollis et al. (WO 93/22678) in view of Agladze and Wohlstädter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, because the inventions teach the fabrication/utility of electrochemical biosensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a processor/computer to analyze the generated device signals as taught by Wohlstadter et al. in the apparatus/device of Hollis et al. (WO 93/22678) in view of Agladze to perform analyte detection because Wohlstadter et al. indicate that "computer controlled voltage systems" are advantageous.

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Specifically the computer/processor can be used to select a particular electrical potential or a particular range of electrical potentials over a predetermined time. Column 24 line 63 to column 25 line 5.

One of ordinary skill would have been motivated to do this in order to control the device reaction parameters and produce accurate/reproducibly data analyses in rapid time.

Response to Arguments

10. Applicant contends that Hollis et al. do not teach the instant invention because a passivation agent is not disclosed. This argument was carefully considered but not found persuasive because Hollis et al. disclose sensor array probes including a passivation layer (passivation agent monolayer) on page 29 lines 27-30 and in figure 26.

With respect to the examiner indicating that Hollis et al. do not teach passivation layers on page 6 of the office action mailed 10/25/04, it is noted that page 6 refers to the rejection of claims 22-23 and 31-33 under 35 USC 103 and the missing limitation from Hollis et al. regarded the inclusion of insulators and/or conductive oligomers along with the passivation agent.

Applicant argued that Hollis et al. did not teach passivation layers comprising two species. This argument was found persuasive and the rejection over Hollis et al. under 35 USC 102 (b) was removed. However, Hollis et al. has been cited under 35 USC 103(a) in view of Agadze.

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Applicant argues that the rejections are not proper because Hollis et al. do not teach passivation agents. However, this argument has been addressed *a priori*. Hollis et al. disclose sensor array probes including a passivation layer (passivation agent monolayer) on page 29 lines 27-30 and in figure 26.

Applicant contends that the examiner has not supported the obviousness rejections with factual evidence. This argument was carefully considered but not found persuasive because each rejection under 35 USC 103 (a) is supported by way of specific references to pages and line number in each cited art. The rejections are maintained.

In response to applicant's argument that Kaymen, Kossovsky, and Wohlstadter are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all the cited art teach electrode devices having coated materials thereon. The rejections are maintained.

Applicant contends that the reference of Wohlstadter is not analogous art because it does not teach a processor configured to receive electrochemical signals, however the claims merely read on a processor to receive an output signal. The rejection is maintained.

11. For reasons aforementioned, no claims are allowed.

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12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

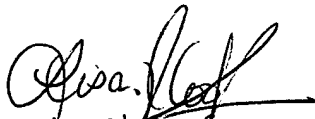
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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Lisa V. Cook

Patent Examiner

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7/8/05



LONG V. LE

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600

07/21/05